## REMARKS

Claims 1, 3-22, and 24-29 are pending in the application.

All the pending claims were rejected in the Office Action, under 35 U.S.C. §103(a), as being unpatentable over Barbachyn *et al.* (US Pat No. 5,688,792), Borgulya *et al.* (US Pat No. 5,574,055), Kaplan *et al.* (US Pat No. 4,727,070), and Miyauchi (US Pat No. 4,900,730). This was the only ground for rejecting any of the present pending claims set forth in the Office Action. Applicants respectfully traverse this rejection, for the following reasons.

As was noted in response to the two preceding Office Actions, in order for any claim to be unpatentable over one or more prior art references, under 35 U.S.C. § 103(a):

> "[A]ll the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)." MPEP 2143.03.

The present application includes two independent claims, claim 1 and claim 21. Claim 1 is directed to:

> "A pharmaceutical composition, comprising at least one oxazolidinone antibacterial drug in a solid particulate form dispersed in a pharmaceutically acceptable carrier in which the at least one oxazolidinone is poorly soluble, wherein the oxazolidinone antibacterial drug is no more than sparingly soluble in water, said composition being adapted for rectal administration, wherein the at least one oxazolidinone antibacterial drug is a compound of formula (I) . . . . or a pharmaceutically acceptable salt thereof." (Language of claim 1; structure of formula (I) omitted; underlining added)

Claim 21 is directed to a method of treatment or prevention of a gram-positive bacterial infection comprising providing a pharmaceutical composition, etc, wherein the description of the "pharmaceutical composition" is the same as that for claim 1, above. Applicants respectfully submit that none of the references cited in the Office Action, weather viewed alone or in combination with each other, teach or suggest a suppository formulation wherein at least one oxazolidinone drug having the characteristics set forth in

claim 1 (e.g., no more than sparingly soluble in water, with a structure of Formula I) is in a solid particulate form dispersed in a pharmaceutically acceptable carrier. (underlined language common to claims 1 and 21).

Barbachyn *et al.* is described in the Office Action as disclosing oxazolidinone compounds having "an identical structure to the compounds of the present invention." (Office Action, p. 2, citing Abstract) Barbachyn *et al.* is also described in the Office Action as disclosing capsules, which "could be manipulated within the level of skill in the art to be used rectally." (Office Action, p. 3) Borgulya *et al.* is described as disclosing "a suppository formulation comprising an oxazolidinone antimicrobial agent." (*Id.*, p. 3, citing Example A). Kaplan *et al.* is described as disclosing "a suppository formulation comprising oxazolidinone compounds, where the lipophilic carrier is a hard fat." (*Id.*, p. 3, citing Example 7). Miyauchi *et al.* is described as disclosing a rectal suppository of antibacterial agents, wherein the agents are "micronized from 1-50 microns, and dissolved in the hard fat Witepsol H-15." (*Id.*, p. 3, citing col. 5, lines 24-64, and Examples)

None of the four references cited, above, expressly discloses even a single suppository wherein an active agent is present in the suppository in a solid particulate form, dispersed in a pharmaceutically acceptable carrier. Barbachyn *et al.* states that one could make capsules or even suppositories of the oxazolidinone antibacterial agents disclosed therein; but, provides no indication that the oxazolidinone is to be present in any such formulation in solid particulate form. Borgulya *et al.* and Kaplan *et al.* each provide hypothetical examples of suppositories, and include details regarding the amount of active agent and carrier to be used in each example; but, neither states nor implies that the active agent is present in the suppository in solid particulate form. Neither of the active agents used in the hypothetical examples of these last two references is an oxazolidione antibacterial agent of Formula I of the present claims. As is noted in the Office Action, the antibacterial agents in the rectal suppositories disclosed in Miyauchi are clearly dissolved therein. In other words, even if one of ordinary skill in the art were somehow motivated to use an oxazolidinone antibacterial agent of Barbachyn *et al.*, micronize the agent as disclosed by Miyauchi, and to incorporate the micronized agent

into a suppository of Borgulya *et al.* and/or Kaplan *et al.*, there is no reason to believe that same individual would select a carrier composition and production conditions that would result in the active agent being present in the carrier in solid particulate form.

Applicants submit, furthermore, that this same element of the present pending claims is not inherently present in the combination of references cited above. The MPEP states that:

> "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). 'To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).
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> 'In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.' *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)." Parenthetical case commentaries omitted." (MPEP Section 2112 IV)

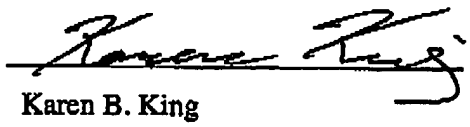
In the present case, Applicant respectfully submits that the limitation in each of the independent claims of the present application, that the oxazolidinone antibacterial agent in the formulation be present in a solid particulate form dispersed in a pharmaceutically acceptable carrier does not necessarily flow from the combined teachings of the four references cited above.

For reasons set forth above, therefore, Applicants respectfully traverse the rejection of claims 1, 3-22, and 24-29, under 35 U.S.C. §103(a) as being unpatentable over Barbachyn *et al.*, Borgulya *et al.*, Kaplan *et al.*, and Miyauchi.

## SUMMARY

Applicants respectfully request reconsideration of the claims 1, 3-22, and 24-29, in view of the remarks, above. Applicants respectfully submit that all of present pending claims are in condition for allowance, for reasons given above. Issuance of all the claims is, therefore, requested. The Examiner is invited to contact the undersigned at the telephone number given below, should he wish to discuss the present amendment and suggest changes to the claims in order to further prosecution of the application.

Dated: 9/29/04



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